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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/655,911

09/05/2003

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EXAMINER

CHANNAVAJJALA, LAKSHMI SARADA

ART UNIT

PAPER NUMBER

1611

MAIL DATE

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01/06/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/655,911	Applicant(s) ANGEL ET AL.	
	Examiner Lakshmi S. Channavajjala	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 October 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4 and 11-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1,3-4 and 11-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt of RCE, amendment and remarks dated 10-16-09 is acknowledged.

Claims 1, 3 and 4 are pending in the instant application. Claims 2 and 5-10 have been cancelled.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10-16-09 has been entered.

Response to Arguments

2. Applicant's arguments with respect to claims 1 and 3-4 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1, 3-4 and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,962,532 to Campbell in view of Wholehealthmd, US 6,114,290 to Lyle et al (Lyle), US 5,523,017 to Moran et al and US 5,910,512 to Conant.

ALTERNATIVELY,

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5. Claims 1, 3-4 and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0002406 Robbins et al (PTO-1449 of 3-14-08) in view of Wholehealthmd, US 6,114,290 to Lyle et al (Lyle), US 5,523,017 to Moran et al and US 5,910,512 to Conant.

Campbell teaches methods and compositions for treating pain at a specific site with an effective amount of capsaicin. Campbell teaches that while capsaicin is effective in pain treatment, the side effects of capsaicin include activation of nociceptors in peripheral tissues desensitization of peripheral nociceptors, cellular degeneration of sensitive A-fiber and C-fiber etc (col. 1, col. 3-4). In order to overcome the above effects, Campbell teaches that anesthesia is first provided to the site where capsaicin needs to be administered, followed by administration of capsaicin (summary of invention). Additionally, Campbell states that any irritant effect of capsaicin is relieved by administering a narcotic analgesic (see claim 9 of Campbell). Campbell fails to teach the claimed kit and also fails to teach the second component of instant claims.

Robbins teaches application of capsaicin or its analogs for treating pain, including neuropathic pain. Robbins teaches capsaicin or its analogue is applied to the skin in the form of a transdermal patch containing greater than 5% to 10% capsaicin (0008-0010; 0012). The steps of application in example 1 describes applying an anesthetic (ELMA- see 0012 for description), followed by capsaicin and removal of the capsaicin. Instant description at 0045 describes the same capsaicin anesthetics as that of Robbins. Robbins teaches that while capsaicin is effective in treating neuropathic pain, it also causes side effects such as burning and therefore suggests applying a

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desensitizer of C fibers, such as an aesthetic so the burning would be reduced. Robbins fails to teach the claimed kit and a second component (polyethylene glycol) to solubilize capsaicin and the instructions of use.

Wholehealthmd teaches a capsaicin product for relieving pain and arthritis. The reference suggests that capsaicin causes stinging and burning sensation, and suggests washing the hands thoroughly after applying the cream, with soapy water (page 3, special concerns). Wholehealthmd does not mention the solubility of capsaicin.

Lyle teaches a detergent composition comprising an aqueous composition that removes oily and soil substances from the skin and cleanse. The composition (given in examples) of Lyle recites polyethylene glycol 400 as a removal agent to remove oil and also soil (col. 6, L 37-67) and Carbopol (in particular see the composition in col. 10, example 3) in an amount of 30 weight % and 1.33 weight % respectively. The composition of Lyle has been adjusted to pH 7.0 and is hence within the claimed range. Lyle teaches an amount of 1 to 70% (which overlaps with the claimed 60-99%), suggesting that the compound is effective in removing the soil and oily substances from skin over a wide range of percentages.

Moran teaches a cleansing bar comprising 70% to 80% polyethylene glycol (which overlaps with the claimed 60-99%), as a base, which may be a mixture of PEG of different molecular weights such as PEG 6000, 8000 and 400 (col. 1 and examples). Moran describes several advantages of including polyethylene glycol base in the soap composition such as good solubility in warm water, non-volatile, stable, physiologically

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safe and non-toxic, ecologically safe, miscibility etc., and further suggests a pH of up to 9 (col. 5, L 1-4).

It would have been obvious for one of an ordinary skill in the art at the time of the instant invention to include a second component such as cleansing or detergent composition of Moran or Lyle respectively, in the composition containing capsaicin of Campbell or Robin to solubilize and remove the residual capsaicin because Wholehealthmd suggests removing capsaicin to avoid burning and stinging, and Moran and Lyle teaches polyethylene glycol as solubilizer for oily substances and for stability, non-toxicity and safety.

A skilled artisan would have expected to reduce burning caused by capsaicin of Campbell, by 1) desensitizing with an anesthetic as well as 2) removing the burning pain caused by capsaicin from the skin with soaps or detergents containing PEG.

While the cited references fail to teach a kit and a separately packaged second composition with the claimed solubility of capsaicin in the second composition, it would have been obvious for a skilled artisan to first apply capsaicin for its intended pharmacological effect and then apply a soap or a detergent containing appropriate amounts of PEG to remove the irritant effect of capsaicin. With respect to the time period to remove PEG, a skilled artisan would have realized from the teachings of Robins, Campbell and Wholehealthmd that even though capsaicin has analgesic effect, the burning sensation caused by capsaicin needs to be neutralized. Further, a skilled artisan employing soap or detergent (Moran and Lyle) would not retain the soap or

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detergent composition on the skin for too long after its intended use to remove the dirt or soil and would wash it off of the skin.

Response to Arguments

6. Applicant's arguments filed 10-16-09 have been fully considered but they are not persuasive.

7. Applicants' arguments regarding Ann Jones are moot because the reference is no longer applied. Applicants argue that various compositions are known to be employed for treating "chili burn" but none of them teach 60-99 percent polyethylene glycol. Applicants argue that Robbins fail to teach the second component in the kit. However, instant rejection is made over a combination of Moran or Lyle and Wholehealthmd with Campbell or Robbins. A skilled artisan would have realized from the teachings of Robbins, Campbell and Wholehealthmd that even though capsaicin has analgesic effect, the burning sensation caused by capsaicin needs to be neutralized. Further, a skilled artisan employing soap or detergent (Moran and Lyle) would not retain the soap or detergent composition on the skin for too long after its intended use to remove the dirt or soil and would wash it off of the skin.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -5.30 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila G. Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lakshmi S Channavajjala/
Primary Examiner, Art Unit 1611
January 3, 2010